

- (c) transiently expressing the unidentified nucleic acid inserts in said infected plant hosts;
- (d) determining one or more phenotypic or biochemical changes in said plant hosts;
- (e) identifying said recombinant viral nucleic acids that result in said one or more phenotypic or biochemical changes in said plant host;
- (f) identifying donor genes or plant host genes associated with said one or more phenotypic or biochemical changes; whereby a positive sense functional gene profile of said plant host or said donor organism is compiled.

Cancel Claims 58 and 59.

### **REMARKS**

#### **The Amendments**

Claim 45 is amended to clarify the meaning of a functional gene profile. Claim 45 is also amended to include the steps of Claims 58 and 59.

No new matter is added in any of the above amendments. The amendments are made in response to the Final Office Action. Applicants believe that the amendments will overcome the rejection or place the claims in a better form for appeal.

The amendments that add the identifying step (f) were presented before in the now canceled Claims 58 and 59; therefore, the amendments do not raise a new issue or require a new search. The Examiner is respectfully requested to enter the amendments and reconsider the application.

#### **Remarks**

##### **1. Provisional double patenting rejection**

Claim 45 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 45 of copending Application No. 09/359,305. Applicants are submitting herewith a Terminal Disclaimer to overcome this rejection.

Claim 45 is also provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 43 of copending Application No. 09/359,297. Applicants are submitting herewith a second Terminal Disclaimer to overcome this rejection.

Claims 45 and 58-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 41, 43-45 and 57 of copending Application No. 09/359,301. Applicants are submitting herewith a third Terminal Disclaimer to overcome this rejection.

**2. 35 U.S.C. § 112, second paragraph rejection.**

Claims 45 and 58-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 58 and 59 are canceled. The rejections to the remaining claims are overcome in parts in view of the amendments, and traversed in parts.

The Examiner states that Claim 45 is vague and indefinite in that the metes and bounds of the phrase "functional gene profile" are unclear. In the Summary of Invention, the present invention is described as a method of making a functional gene profile in an organism by transiently expressing a nucleic acid sequence library in a host plant, determining the phenotypic or biochemical changes in the host plant, identifying a trait associated with the change, identifying the donor gene associated with the trait, and identifying the homologous host gene, if any.

A functional Gene Profile is defined as a collection of genes of an organism which code for a biochemical or phenotypic trait. The functional gene profile of an organism is found by screening nucleic acid sequences from a donor organism by over expression or suppression of a gene in a host organism. Therefore, a functional gene profile will depend upon the quantity of donor genes capable of causing over-expression or suppression of host genes or of being expressed in the host organism in the absence of a homologous host gene (see definition at page 35).

**A functional gene profile does not have a fixed number of genes because it depends upon the quantity of donor genes capable of causing a biochemical or a phenotypic change.** However, a functional gene profile does have a finite number of genes as it is limited by all the genes in the genome of a donor organism. A method of compiling a positive sense functional gene profile of an organism starts with the step of preparing a library of DNA or RNA sequences from a donor organism, and constructing recombinant viral nucleic acids each comprising an unidentified nucleic acid insert obtained from said library in a positive sense orientation. All of the RNA/DNA sequences from the library are used to construct recombinant viral nucleic acids. Then all of the recombinant viral nucleic acids are used to infect a host plant. Genes identified with a phenotypic or biochemical change is compiled as a functional gene profile of the donor organism or the plant host. The present invention claims a method compiling a positive sense functional gene profile comprising the steps of (a)-(f). Each step is clear and definite. Following the steps (a)-(f), a functional gene profile is compiled. There is no need to indicate the number of genes identified in order to satisfy the claim limitation of being a "functional gene profile."

Applicant is submitting herewith a Declaration pursuant to 37 CFR 1.132 by Dr. Della-Cioppa to illustrate how a functional gene profile can be compiled based on Claim 45. In the working example provided by Dr. Della-Cioppa, a cDNA library of *Arabidopsis thaliana* was prepared. All of the cDNA sequences from the library were used to construct recombinant viral nucleic acids. The recombinant viral nucleic acids were used to infect 8000 *Nicotiana benthamiana* host plant. The host plants with a dwarf phenotype were identified. The 109 cDNAs sequences that cause the dwarf phenotype were subsequently identified. The collection of these 109 DNA sequences compiles the functional gene profile.

Claim 45 distinctly claims a method of compiling a functional gene profile. Each step of the method is clear and definite, as illustrated by the working example in Dr. Della-Cioppa's Declaration. Applicant respectfully requests the Examiner to withdraw the rejection.

The Examiner states that Claim 45 is vague and indefinite in that there is no clear

and positive antecedent basis for the phrase "said one or more changes" in step (e). Applicants have amended step (e) in Claim 45 to recite "said one or more phenotypic or biochemical changes". Therefore, this rejection is overcome in view of the amendment.

Claim 45 is rejected as being incomplete for omitting essential steps. Applicants have amended Claim 45 to add a step to recite identifying donor genes or plant host genes associated with said one or more phenotypic or biochemical changes. Therefore, this rejection is overcome in view of the amendment.

In view of the above amendments, the rejections of Claim 45 and Claims 60-70 should be withdrawn.

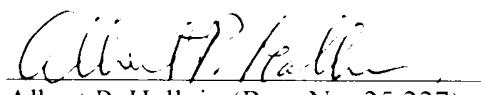
Therefore, the §112, second paragraph, rejection of claims 45, and 60-70 should be withdrawn.

### CONCLUSION

In view of the foregoing amendments and remarks, the Applicants believe the application is in good and proper condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 463-8109.

Respectfully submitted,

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**MARKED -UP VERSION TO SHOW CHANGES MADE IN THE CLAIMS**

45. (Four Times Amended) A method of compiling a positive sense functional gene profile of an organism comprising:

- (a) preparing a library of DNA or RNA sequences from a non-plant donor organism, and constructing recombinant viral nucleic acids each comprising an unidentified nucleic acid insert obtained from said library in a positive sense orientation;
- (b) infecting [a] plant hosts with [one or more] said recombinant viral nucleic acids;
- (c) transiently expressing the unidentified nucleic acid inserts in said infected plant hosts;
- (d) determining one or more phenotypic or biochemical changes in said plant hosts;
- (e) identifying said recombinant viral nucleic acids that result[s] in said one or more phenotypic or biochemical changes in said plant host;
- (f) identifying donor genes or plant host genes associated with said one or more phenotypic or biochemical changes; [repeating steps (b)–(f) until] whereby a positive sense functional gene profile of said plant host or said donor organism is compiled.

Cancel Claims 58 and 59.